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EXAMINER	
WHITEMAN, BRIAN A	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/818,943	ERIKSSON ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 5/24/04.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1,5-9,12,14,15,18-20,22-25,29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) 5 is/are allowed.

6)☒ Claim(s) 1,6,7,8,9,12,14,15,18,19,20,22,23,24,25,29 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Final Rejection

Claims 1, 5-9, 12, 14, 15, 18, 19, 20, 22, 23, 24, 25, and 29 are pending.

Applicants' traversal, the amendment to claims 1, 5, 12, 15, 18-20, 22-25, and 29 in paper filed on 5/24/04 is acknowledged and considered.

Specification

The disclosure is objected to because of the following informalities: the status (e.g., pending, abandoned, patented US Patent No.) of US applications listed on page 7, line 20 and 22 is missing.

Claim Objections

Claim 24 is objected to because of the following informalities: the term "moust" is misspelled on line 8. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described

in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation 'control cell' in amended claim 22 is not supported by the as-filed specification. Applicant has not pointed out where the amended claim is supported, nor does there appear to be a written description of the claim limitation 'control cell' in the application as filed. See MPEP § 2163.06. The only part of the specification that might be associated with the amended claim is found on page 30, lines 18-27 (Example 9) of the specification. In this example, the applicants discuss using a cell or cells isolated from a transgenic non-human animal, which over-expresses PDGF-C and monitoring the biological activity of the cell or cells when exposed to a compound. The example does not explicitly recite comparing the cell or cells to a control cell. The statement "An inhibition of PDGF-C biological activity indicates the compound may be useful as a PDGF-C antagonist (page 30, lines 26-27)," indicates that the cell or cells would be compared to something. However, the specification does not disclose what would be compared with the cell or cells, e.g., the same cell before/after the exposure to a compound; a cell from a wild-type animal; a cell from the same transgenic animal but not exposed to the compound; a cell from a different transgenic non-human animal.

Claims 1, 6-9, 12, 14, 15, 18-20, 22-25, and 29 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic mouse whose genome comprises a transgenic DNA comprising a polynucleotide sequence operably linked to an alpha myosin heavy chain promoter, wherein the polynucleotide sequence encodes a polypeptide comprising the amino acid sequence SEQ ID NO: 1 or SEQ ID NO: 2, wherein the transgenic

mouse over-expresses the polypeptide and develops myocyte hypertrophy or heart fibrosis, does not reasonably provide enablement for making and using a transgenic mouse whose genome comprises a transgenic DNA encoding a polynucleotide sequence operably linked to a different promoter, wherein the polynucleotide sequence encodes a polypeptide comprising the amino acid sequence SEQ ID NO: 1 or SEQ ID NO: 2 that over-expresses a polypeptide having a PDGF-C and develops myocytes hypertrophy or heart fibrosis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claimed invention is directed to making and using a transgenic mouse whose genome comprises a transgenic DNA comprising a polynucleotide sequence operably linked to a suitable promoter, wherein the polynucleotide sequence encodes a polypeptide comprising the amino acid sequence SEQ ID NO: 1 or SEQ ID NO: 2 that over-expresses a polypeptide having a PDGF-C and develops myocytes hypertrophy or heart fibrosis. The field of the invention is directed to producing a transgenic mouse with a desired phenotype.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation (United States v. Telectronics, Inc., 8 USPQ2d 1217 (Fed. Cir. 1988). Whether undue experimentation is required is not based upon a single factor, but rather a conclusion reached by many factors. These factors were outlined in Ex parte Forman, 230

USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in In Re Wands (see above) and include the following:

The prior art teaches that the art of transgenic is not predictable art with respect to transgene behavior and the resulting phenotype. While the state of the art of transgenics is such that one of skill in the art would be able to produce transgenic mouse comprising a transgenic DNA encoding PDGF-C; it is not predictable if the transgene would be expressed at a level and specificity sufficient to cause a particular phenotype. For example, the level and specificity of expression of a transgene (e.g. PDGF-C) as well as the resulting phenotype of the transgenic mouse are directly dependent on the specific transgene construct. The individual gene of interest, coding, or non-coding sequences present in the transgene construct, the specificity of transgene integration into the genome, for example, are all important factors in controlling the expression of a transgene in the production of genetically modified animals, which exhibit a particular phenotype. This observation is supported by Wall (Theriogenology, 1996) who states "Our understanding of essential genetic control elements makes it difficult to design transgenes with predictable behavior." See page 61, last paragraph. See also Houdebine (Journal of Biotechnology, 1997) who discloses that in the field of transgenics, constructs must be designed case by case without general rules to obtain good expression of a transgene (page 275, column 1, 1st paragraph); e.g. specific promoters, presence or absence of introns, etc. With regard to the importance of promoter selection, Niemann states that, "the transgenic pigs made with different promoters regulating expression of a growth hormone gene give disparate phenotypes- one deleterious to the pig, the other compatible with pig health (Transg. Res., 7:73-75, 1997)."

Furthermore, Sigmund teaches that the random nature of transgene insertion, resulting founder mice can contain the transgene at a different chromosomal site, and that the position of the transgene effects expression, and thus the observed phenotype (Arteroscle. Throm. Vasc. Biol. 20: 1426, 2000).

The specification recites that the invention features a genus of transgenic non-human mammals, which over-expresses PDGF-C and goes on to contemplate that there are two techniques for producing the transgenic non-human mammals (page 9, lines 25-31). The specification cites prior art pertaining to methods for generating transgenic mice using fertilized eggs and pro-nuclei injection (page 20). In addition, the as-filed specification provides the second method for producing transgenic mice, which involves modification of embryonic stem cells using transgenic DNA (pages 21-23). The applicant produces a transgenic mouse whose genome comprises a transgenic DNA comprising a polynucleotide sequence operably linked to an alpha myosin heavy chain promoter, wherein the polynucleotide sequence encodes a polypeptide comprising the amino acid sequence SEQ ID NO: 1 or SEQ ID NO: 2, wherein the transgenic mouse over-expresses the polypeptide and develops myocytes hypertrophy or heart fibrosis, wherein the mouse is heterozygous for the transgenic DNA. The applicants contemplate that the transgenic mice can be used in a method for identifying PDGF-C antagonist, compounds that inhibit hypertrophy, and compounds that inhibit cardiac fibrosis (pages 30-31).

The claims embrace making and using a transgenic mouse whose genome comprises a transgenic DNA comprising a polynucleotide sequence operably linked to a suitable promoter or a promoter that is capable of directing expression of the polynucleotide in heart, wherein the polynucleotide sequence encodes a polypeptide comprising the amino acid sequence SEQ ID

NO: 1 or SEQ ID NO: 2, wherein the transgenic mouse over-expresses the polypeptide and develops myocytes hypertrophy or heart fibrosis.

In view of the In Re Wands Factors, the claimed invention is enabled for a transgenic mouse whose genome comprises a transgenic DNA comprising a polynucleotide sequence operably linked to an alpha myosin heavy chain promoter, wherein the polynucleotide sequence encoding a polypeptide comprising the amino acid sequence SEQ ID NO: 1 or SEQ ID NO: 2, wherein the transgenic mouse over-expresses the polypeptide and develops myocytes hypertrophy or heart fibrosis. However, the claimed invention is not enabled for full scope of the claimed invention. The specification does not teach one skilled in the art how to make and use the full scope of the claimed invention. The applicants teach using an alpha myosin heavy chain promoter for producing the claimed transgenic mouse. The applicants cite an example of a promoter for three different tissues (page 11). The only promoter cited for cardiac myocytes specific expression was the alpha-myosin chain promoter. However, the specification and the prior art do not provide evidence that the alpha myosin heavy chain promoter is considered representative of a genus of suitable promoters or a genus of suitable promoters that are capable of directing expression of the polynucleotide in the heart. The specification does not teach one skilled in the art how to use a genus of suitable promoter in the transgenic DNA for producing the claimed transgenic mouse. The prior art teaches that individual gene of interest, coding, or non-coding sequences present in the transgene construct, the specificity of transgene integration into the genome, for example, are all important factors in controlling the expression of a transgene in the production of genetically modified animals, which exhibit a particular phenotype. Constructs must be designed case by case. See Niemann, *supra*. Therefore, the

specification does not provide sufficient guidance and/or factual evidence for one skilled in art to reasonably correlate from the transgenic mouse produced in the specification using the specific construct to practicing the full scope of the claimed invention without undue and excessive experimentation.

In conclusion, in view of the quantity of experimentation necessary, the prior art for making a transgenic mouse over-expressing a polypeptide with a desired phenotype, the lack of direction or sufficient guidance provided by the as-filed specification for the production of the claimed transgenic mouse using a genus of promoters suitable for expression in the heart, the claimed invention is only enabled for a transgenic mouse whose genome comprises a transgenic DNA comprising a polynucleotide sequence operably linked to an alpha myosin heavy chain promoter, wherein the polynucleotide sequence encodes a polypeptide comprising the amino acid sequence SEQ ID NO: 1 or SEQ ID NO: 2, wherein the transgenic mouse over-expresses the polypeptide and develops myocytes hypertrophy or heart fibrosis. Furthermore, the working examples for the demonstration or the reasonable correlation to the production of a transgenic mouse other than the mouse taught in the specification, in particular when the expression of the PDGF-C must occur at a level resulting in a corresponding phenotype, the unpredictable prior art with respect to the transgene behavior in transgenic mouse, and the breadth of the claims drawn to using a genus of suitable promoters to produce the claimed transgenic mouse, it would require an undue amount of experimentation for one skilled in the art to make and use the full scope of the claimed invention.

Applicant's arguments filed 5/24/04 have been fully considered but they are not persuasive.

Applicants argue that, "the law is clear that "the test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent couple with information known in the art without undue experimentation." see United States v. Teletronics. Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1233 (Fed. Cir. 1988)". Applicants further argue, that, "The office action is correct that the art of producing transgenic mice may be unpredictable and it may involve a lot of trial and error screening to obtain an animal with the desired phenotype. Significantly, even using the alpha-MHC promoter and SEQ ID NO: 1 or 2 without using the specific mouse exemplified in the instant specification, a person of ordinary skill in the art of transgenic mouse production will still have to expend a large amount of time and resources to produce a transgenic mouse having the desired phenotype (i.e., a mouse as claimed in claim 5. This is the type of effort routinely expended in this art." Applicants further argue that, "There is no evidence or any basis to assert that simply changing to a different yet similar promoter (many of which are known and readily available to the ordinary skilled artisan) would require significantly more experimentation that would amount to undue experimentation as required under the case law. In other words, if the examiner considers that the method recited in claim 5 is enabled, there is no reason to assert that the method recited in claim 1 is not."

With respect to Applicants' argument that, "a person of ordinary skill in the art of transgenic mouse production will still have to expend a large amount of time and resources to produce a transgenic mouse having the desired phenotype (i.e., a mouse as claimed in claim 5. This is the type of effort routinely expended in this art." The argument is not found persuasive because the specification must be enabling as of the filing date. See MPEP 2164.05(a). In view of the lack of guidance provided by the specification for which promoters would or would not

work in the claimed methods, it would require excessive and an undue amount of experimentation for one skilled in the art to make and use a genus of suitable promoters in the claimed method and determine which promoter in the genus produced the transgenic mouse with the specific phenotype set forth in the claimed method. In addition, In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states:

> Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements, while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved.

This is the case here. The prior art and the specification do not teach a known scientific law for producing a transgenic animal with a desired phenotype. The prior teaches the unpredictability of producing a transgenic animal with a desired phenotype. Applicants teach producing a transgenic mouse with a specific phenotype using the method recited in claim 5. However, the relevance of this data to using a genus of suitable promoters or a genus of suitable promoters that are capable of directing expression of the polynucleotide in the heart to produce the claimed transgenic mouse is unclear at best because neither the applicants nor the prior art provide a correlation or nexus between the results obtained in the working example provide by the applicants with results which the skilled artisan would reasonably expect to observe when using

a genus of suitable promoters or a genus of suitable promoters that are capable of directing expression of the polynucleotide in heart.

Furthermore, with respect to applicants' assertion that, "This is the type of effort routinely expended in this art."

The court in Enzo 188 F.3d at 1374, 52 USPQ2d at 1138 states:

> It is well settled that patent applications are not required to disclose every species encompassed by their claims, even in an unpredictable art. However, there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed.
> In re Vaeck, 947 F.2d 48, 496 & n.23. 30 USPQ2d 1438, 1445 &n23 (Fed. Cir. 1991)(citation omitted). Here, however, the teachings set forth in the specification provide no more than a "plan" or "invitation" for those of skill in the art to experiment...; they do not provide sufficient guidance or specificity as to how to execute that plan. See Fiers v. Revel. 984 F.2d.1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993); In re Wright, 999 F.2d...[1557], 1562, 27 USPQ2d...[1510], 1514. [Footnote omitted].

On this record, it is apparent that the specification provides no more than a plan or invitation in view of the prior art exemplifying the unpredictability of making a transgenic animals and obtaining a desired phenotype, for those skilled in the art to perform undue and excessive experimentation with different promoters so as to provide the claimed transgenic mouse with the desired phenotype as intended by the as-filed specification at the time the invention was made.

With respect to applicants' argument that, "There is no evidence or any basis to assert that simply changing to a different yet similar promoter (many of which are known and readily available to the ordinary skilled artisan) would require significantly more experimentation that would amount to undue experimentation as required under the case law. In other words, if the examiner considers that the method recited in claim 5 is enabled, there is no reason to assert that the method recited in claim 1 is not." The argument is not found persuasive because the rejection of record cites several prior art references teaching the unpredictability of producing a

transgenic animal with a desired phenotype. See Wall, Niemann, and Houdebine. Applicants teach producing a transgenic mouse with a specific phenotype using the method recited in claim 5. However, the relevance of this data to using a genus of suitable promoters or a genus of suitable promoters that are capable of directing expression of the polynucleotide in the heart to produce the claimed transgenic mouse is unclear at best because neither the applicants nor the prior art provide a correlation or nexus between the results obtained in the working example provide by the applicants with results which the skilled artisan would reasonably expect to observe when using a genus of suitable promoters or a genus of suitable promoters that are capable of directing expression of the polynucleotide in heart. MPEP 2164.02 recites, "Proof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation." This is the case here. The rejection of record displays that it would be undue experimentation for one skilled in the art to use a genus of suitable promoters or a genus of suitable promoters that are capable of directing expression of the polynucleotide in the heart to make the claimed transgenic mouse. Given the above analysis of the factors which the courts have determined are critical in determining whether a claimed invention is enabled, it must be concluded that the skilled artisan would have need to have conducted undue and excessive experimentation in order to practice the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 6, 7, 8, 9, 14, 15, 18, 20, 22, 23, 24, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: active steps required for a promoter that is **capable** of directing expression of the polynucleotide in the heart. The claims do not define the active steps if the promoter is not capable of expressing the polynucleotide sequence in the heart.

Claims 6, 7, 8, 9, 14, 15, 18, 20, 22, 23, 24, and 25 are also rejected under 112 second paragraph because the claims are dependent from claims 1 and 18.

Conclusion

Claim 5 is in condition for allowance because the claim is free of the prior art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Scott D. Priebe

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PRIMARY EXAMINER

Patent Examiner, Group 1635